

# Ventolin®

## Prescribing information

**Indications:** To relieve bronchospasm in: bronchial asthma of all types, chronic bronchitis, other chronic bronchopulmonary disorders in which bronchospasm is a complicating factor.

**Contraindications:** Hypersensitivity to any of the ingredients and tachyarrhythmias. Ventolin Respirator Solution is not recommended for use in children under 12 years of age, until the dose regimen and evidence concerning its safety have been established.

**Warnings:** The safety of salbutamol in pregnancy has not been established. Care should be taken with patients suffering from myocardial insufficiency, arrhythmia, hypertension, diabetes mellitus, or thyrotoxicosis. The use of Ventolin Respirator Solution by means other than IPPV is not recommended until the safety and the dosage regimen for alternate methods of delivery have been established. Occasional patients have been reported to have developed severe paradoxical airway resistance with repeated excessive use of sympathomimetic inhalation preparations. The cause of this refractory state is unknown. It is advisable that in such instances the use of the preparation be discontinued immediately and alternate therapy instituted, since in the reported cases the patients did not respond to other forms of therapy until the drug was withdrawn. Fatalities have been reported following excessive use of sympathomimetic amines by inhalation, the exact cause of which is unknown. Cardiac arrest was noted in several instances.

**Precautions:** Use with caution in patients sensitive to sympathomimetic amines. Other beta-adrenergic drugs, e.g. isoprenaline should not be given concomitantly.

**Adverse Reactions:** An increase in heart rate may occur in patients who inhale large doses of Ventolin. No electrocardiographic changes were observed (Choo-Kang et al 1970). Other side effects which may occur with Ventolin are peripheral vasodilatation, fine tremor of skeletal muscles, headache, dizziness, nausea, palpitation and unpleasant taste in the mouth.

**Dosage and Administration: Ventolin Inhaler:** One or two inhalations repeated every four hours, if required. More than eight inhalations per day is not recommended. **Ventolin Tablets:** All doses to be taken three or four times daily by children and adults. **Adults:** 2 mg-4 mg. The optimum single dose for most adult patients is 4 mg. With elderly patients or with patients who are unusually sensitive to beta-adrenergic stimulants, it is advisable to initiate treatment with 2 mg. **Children:** 6-12 years: 2 mg; over 12 years: Adult dosage.

**Ventolin Respirator Solution:** Ventolin Respirator Solution should be used only under medical supervision. It has been reported that the use of Intermittent Positive Pressure Ventilation in acute asthma attacks, in several cases was related to lethal episodes of hypoxia and pneumothorax. This method of drug administration may be ineffective in patients with severe obstruction and greatly increased airway resistance, and it may induce severe hypercapnia and hypoxia. During intermittent positive pressure ventilation therapy, the monitoring of arterial blood gases is highly desirable.

**Adult Dosage:** The average dose for a single treatment is 0.25 to 0.50 ml of Ventolin Respirator Solution (containing 1.25 to 2.5 mg of salbutamol), diluted in 5 ml or more of normal saline or distilled water. For more refractory cases, the single dose may be increased to 1 ml. Ventolin Respirator Solution is to be administered through intermittent positive pressure ventilation. The inspiratory pressure is usually 10-20 cm H<sub>2</sub>O and the duration of administration varies from 5 minutes up to 20 minutes dependent upon the patient and the control of the apparatus. Optimally, the duration of treatment is 10 to 15 minutes. This length of administration provides a more gradual and more complete lysis of bronchospasm. If acute bronchospasm persists, treatment may be repeated, at the physician's discretion, three times in 24 hours with a time interval of not less than 3 hours.

**Children Dosage:** Children over 12 years of age may be treated in the same fashion as adults, using a single dose of 0.25 ml of Ventolin Respirator Solution (containing 1.25 mg of salbutamol). Experience is insufficient for recommending the treatment of children under 12.

**Presentation: Ventolin Inhaler:** A metered aerosol, delivering 100 mcg of salbutamol per inhalation. Each 15 ml canister provides at least 200 inhalations. **Ventolin Tablets:** 4 mg. Each tablet contains salbutamol sulphate 4.8 mg, equivalent to salbutamol 4.0 mg. Bottles of 100. 2 mg. Each tablet contains salbutamol sulphate 2.4 mg, equivalent to salbutamol 2.0 mg. Bottles of 100. **Ventolin Respirator Solution:** Contains salbutamol sulphate 0.6% in an aqueous solution, equivalent to 5 mg of salbutamol per ml. Benzalkonium chloride is used for preservative. Available in 15 ml, amber-coloured, glass bottles with neoprene stoppers and polypropylene screw caps. Each bottle contains 10 ml of Ventolin Respirator Solution and is presented in an individual carton with enclosed leaflet. For use in hospital, a 10 x 10 ml pack is available.

# Beclovent®

## Prescribing information

**Indications:** Treatment of steroid-responsive bronchial asthma: (1) In patients who in the past have not been on steroids but the severity of their condition warrants such treatment. (2) In steroid-dependent patients to replace or reduce oral medication through gradual withdrawal of systemic steroids.

**Contraindications:** Active or quiescent untreated pulmonary tuberculosis, or untreated fungal, bacterial and viral infections, and in children under six. Status asthmaticus, and in patients with moderate to severe bronchiectasis.

**Warnings:** In patients previously on high doses of systemic steroids, transfer to BECLOVENT Inhaler may cause withdrawal symptoms such as tiredness, aches and pains, and depression. In severe cases, acute adrenal insufficiency may occur necessitating the temporary resumption of systemic steroids.

The development of pharyngeal and laryngeal candidiasis is cause of concern because the extent of its penetration of the respiratory tracts is unknown. If candidiasis develops the treatment should be discontinued and appropriate antifungal therapy initiated. The incidence of candidiasis can generally be held to a minimum by having patients rinse their mouth with water after each inhalation.

### Precautions:

1. It is essential that patients be informed that BECLOVENT Inhaler is a preventive agent, must be taken at regular intervals, and is not to be used during an asthmatic attack.
2. The replacement of a systemic steroid with BECLOVENT Inhaler has to be gradual and carefully supervised by the physician, the guidelines under Dosage and Administration should be followed in each case.
3. Unnecessary administration of drugs during the first trimester of pregnancy is undesirable. Corticosteroids may mask some signs of infection and new infections may appear. A decreased resistance to localized infection has been observed during corticosteroid therapy. During long-term therapy, pituitary-adrenal function and hematological status should be periodically assessed.
4. Fluorocarbon propellants may be hazardous if they are deliberately abused. Inhalation of high concentrations of aerosol sprays has brought about cardiovascular toxic effects and even death, especially under conditions of hypoxia. However, evidence attests to the relative safety of aerosols when used properly and with adequate ventilation.
5. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.
6. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypoprothrombinaemia.
7. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

**Adverse Reactions:** No major side-effects attributable to the use of recommended doses of BECLOVENT Inhaler have been reported. No systemic effects have been observed when the daily dose was below 1 mg (twenty puffs). Above this dose, reduction of plasma cortisol, indicating adrenocortical suppression, may occur. Therapeutic doses may cause the appearance of *Candida albicans* in the mouth and throat.

The replacement of systemic steroids with BECLOVENT Inhaler may unmask symptoms of allergies which were previously suppressed by the systemic drug. Conditions such as allergic rhinitis and eczema may thus become apparent during BECLOVENT therapy after the withdrawal of systemic corticosteroids.

**Dosage and Administration:** The optimal dosage of BECLOVENT may vary widely and must be individually determined, but the total daily dose should not exceed 1 mg of beclomethasone dipropionate (20 puffs).

**Adults:** The usual dose is two inhalations (100 mcg) three to four times daily. If this dose is not sufficient, it can be doubled initially. As a maintenance dose, many patients do well on two inhalations daily. **Children:** Insufficient information is available to warrant the safe use in children under six years of age. The average daily dose for children over six years of age is 6 mcg/kg of body weight.

**Important:** As a steroid aerosol, *Beclovent Inhaler* is for maintenance therapy. It is not intended to give immediate relief, and effectiveness depends both on regular use and proper technique of inhalation. Patients must be instructed to take the inhalations at regular intervals and not, as with bronchodilator aerosols, when they feel a need for relief of symptoms.

They should also be instructed in the correct method of use, which is to *exhale completely* then place the lips tightly around the mouthpiece. The aerosol should be actuated as the patient *breathes in deeply and slowly*. This ensures maximum penetration into the lungs, and the breath should be held as long as possible following each inhalation.

The patient's attention should be drawn to the instruction Sheet, enclosed in each BECLOVENT pack.

In the presence of excessive mucus secretion, the drug may fail to reach the bronchioles. Therefore, if an obvious response is not obtained after ten days, attempts should be made to remove the mucus with expectorants and/or with a short course of systemic corticosteroid treatment.

Careful attention must be given to patients previously treated for prolonged periods with systemic corticosteroids, when transferred to BECLOVENT. Initially BECLOVENT and the systemic steroid must be given concomitantly while the dose of the latter is gradually decreased. The usual rate of withdrawal of the systemic corticoid is the equivalent of 2.5 mg of prednisone every four days if the patient is under close observation.

If continuous supervision is not feasible, the withdrawal of the systemic steroid should be slower, approximately 2.5 mg of prednisone (or equivalent) every ten days. If withdrawal symptoms appear, the previous dose of the systemic drug should be resumed for a week before further decrease is attempted. There are some patients who cannot completely discontinue the oral corticosteroid. In these cases, a minimum maintenance dose should be given in addition to BECLOVENT Inhaler.

**Supplied:** BECLOVENT Inhaler is a metered-dose aerosol delivering 50 micrograms of beclomethasone dipropionate with each depression of the valve. There are two hundred doses in a container. Official product monograph on request.

pitals, but also ambulance services and police and fire departments. Thus, a disaster plan had to be a community plan, involving coordination of all hospitals in the area and integration of their plans with those of the police and fire departments.

The community disaster plans that have been in vogue for the past 10 years have served their purpose; the incorporation of medical disaster teams, as detailed by Gerace, should be considered seriously by all hospitals and communities.

Members of the medical profession, myself included, have always been loathe to initiate treatment in a ditch or on a railroad embankment. The milieu is strange and totally without control. It is time we accepted our responsibility in this area and removed, through practice, the fear, the uncertainty and, above all, the unfamiliarity associated with disasters.

Gerace's article is a timely reminder that the world is mobile, and with mobility the intensity of environmental hostility is enhanced. Two recent incidents in Ontario have demonstrated this very well — the crash of the DC 9 at Toronto International Airport and the refinery fire at Mississauga. It is sobering to think that a jumbo jet could crash anywhere in Canada. Because of Canada's geography such a disaster would probably occur far from a hospital, so that triage and treatment would have to be carried out at the scene to obviate the long delays that would be encountered with previous plans, which called for extrication and transportation from the site.

The plan expounded by Gerace deserves the careful attention of all departments of surgery and disaster committees in Canada.

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## "The Harvard Guide to Modern Psychiatry"

To the editor: "The Harvard Guide to Modern Psychiatry" was graded by Dr. Morton S. Rapp as an excellent

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PAAB  
CCFP

MEMBER  
PMAC

book (*Can Med Assoc J* 120: 133, 1979). He thought the chapter by Gerald Klerman on affective disorders was particularly praiseworthy. In the hope of finding a good reference on affective disorders I looked through my copy of the book. I did not think Klerman's chapter was excellent. Candidates for the Canadian specialty examinations in psychiatry might run into trouble if they reflected the attitude to the biologic aspect of affective disorders that Klerman presents. Rapp indicated that much the same criticism could be applied to the chapter on schizophrenia.

Klerman initially communicates enthusiasm about the advances in the field of affective disorders, including the biochemical findings. However, he concludes that there is not much practical use in trying to distinguish between endogenous and reactive depressions. The lag time between writing a chapter for a book and publication is probably a factor, for it seems that new relevant information has been appearing every month. In the chapter by Schildkraut some pharmacology basic to further clinical work is discussed that indicates that it may be important even to attempt to distinguish varieties of endogenous depression. Tricyclic antidepressants, such as imipramine, are potent in inhibiting the uptake of norepinephrine by presynaptic neurons, while others, such as amitriptyline, are much weaker in this effect but are more potent in inhibiting serotonin uptake. Recent evidence suggests that the depressed individuals who respond to imipramine differ clinically from those who respond to amitriptyline. Klerman did not mention this. This is a particular instance of an omission that seems to be important.

After reading Klerman's chapter I also got the impression that he has not been able to integrate the flow of new findings. In particular, the recent use of lithium carbonate has led to a considerable change in diagnostic psychiatry. Many patients who had been thought to be schizophrenic are responding to lithium, which seems

to indicate that they actually have a manic depressive illness. An extreme example in my experience is that of a man whom, not long ago, I would have thought was a typical catatonic schizophrenic; however, he responded to lithium alone on one occasion and to lithium plus trifluoperazine on another. This is a challenging time. I think Klerman participates in the confusion with his "pluralistic" approach without really helping the student deal with the problems.

A particularly important point Klerman does not mention, although folie circulaire was described a long time ago, is that patients who are manic depressives may be virtually continuously ill. Although most episodes are self-limiting, manic depression can be a chronic illness that is associated with "deterioration". Klerman also failed to mention diurnal mood variation, alcohol abuse as a symptom of mania and treatment of refractory depression.

My sampling of "The Harvard Guide to Modern Psychiatry" is incomplete, but what I have read thus far leads me to hope that the second edition will be much improved. A discussion of psychiatry needs a solid and shorter textbook.

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### **Management of obstetric complications at small rural hospitals**

*To the editor:* I take issue with the conclusion of Dr. Douglas P. Black and Susan Gick that hospitals with fewer than 100 deliveries a year should discontinue all obstetric practice (*Can Med Assoc J* 120: 31, 1979).

There must be many small isolated hospitals, such as the one in my community, in which there are never more than two or three deliveries a month, the doctor is single-handed, and the facilities for such procedures as blood transfusion and cesarean section are nonexistent. Yet obstetrics continues to be practised, as it has for many years, and the inhabitants of the community wish it to continue.

In my community careful prenatal supervision, sharpened by the knowledge that in bad weather or at night the practitioner will have to deliver the infant come what may, results in elective delivery "outside" hospital in about 30% of all cases; in the remainder delivery occurs in hospital, where the only aid is a vacuum extractor and pudendal block.

I do not pretend that such practice is without hazard; however, I deplore the philosophy that unless total care is available all care in that field should be denied. Rather I suggest that every aid to prenatal diagnosis, such as ultrasonography, be available in small isolated hospitals, and that persons practising in these circumstances should have the opportunity to improve their basic skills in obstetrics. In this manner we can help care for the pregnant woman in her community, not only to her satisfaction, but also to the increased well-being and security of the whole community.

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### **Scientific meeting epidemic**

*To the editor:* I enjoyed Dr. Kenneth M. Leighton's light-hearted musings on scientific communications (*Can Med Assoc J* 119: 1139, 1978). Although I cannot argue with much that he says — for instance, none would disagree that all researchers are not blessed with "silver tongues" — I take issue with his basic assumption that there are too many scientific meetings and that they are a waste of time. While this may be true of Dr. Leighton's chosen field, the answer is obvious — don't go. To my knowledge no compulsion exists to attend these meetings. Salaried university staff may be tempted to join the "jet set" by rushing off to meetings in far-flung corners of the globe, but few full-time "fee-for-service" personnel are so attracted. Loss of income is such that few would wish to attend any more than two or three meetings a year.

To improve the quality of large general meetings, the American